

d.) Remarks.

Applicant has amended claims 1-19 and 21-50. Support for the amendments to the claims can be found throughout the original claims and in the specification, Figure Legends and Figures. Although most of the amendments are to correct typographical and grammatical errors, support for the substantive amendments can be found throughout the specification and within the claims themselves either as originally filed or as subsequently amended. For example, support for the amendments to claims 1 and 11 can be found in the specification at Paragraphs 0027-0028 and claim 27 (“non-bactericidal”), and also in the specification at Paragraph 0044 and claim 22 (“prevent binding of ... germs”), and claim 23 (“improvement of the natural barrier function of skin”). Support for the amendments to claim 5 can be found in Paragraph 0020 and Example 1, and also claim 12. Support for the amendments to claim 7 can be found in Paragraphs 0019-0024 and Examples 1-9, and also claims 12-15. Support for the amendments to claim 10 can be found in Paragraphs 0022 and 0044, and claims 22-25. No new matter and no new issues are raised with these amendments, and their entry is respectfully requested. Currently, claims 1-19 and 21-50 are pending.

Remarks Regarding Claim Objection

Claims 1-19, 21-34 and 36-49 stand objected to for lacking the word “a” or “the” prior to the word “composition” or “method.” Application has amended the claims to recite “A composition ...” or “A method ...” as appropriate. Thus, this objection is moot.

Remarks Regarding 35 U.S.C. § 112, Second Paragraph

Claims 16 stands rejected, under 35 U.S.C. § 112, second paragraph, as allegedly indefinite. Applicant respectfully traverses this rejection.

Specifically, the Examiner objects to the phrase “said active substance” as having insufficient antecedent basis. This phrase has been deleted and the rejection is moot.

Remarks Regarding 35 U.S.C. § 103(a)

Claims 1-19 and 21-50 stand rejected, under 35 U.S.C. § 103(a), as allegedly obvious over Müller et al. (European Journal of Pharmaceutics; “Müller”) in view of Kreitlow et al. (Journal of Biotechnology; “Kreitlow”), further in view of Caudales et al. (International Journal of Systematic and Evolutionary Biology, “Caudales”), further in view

of Jacob et al. (Life Sciences, “Jacob”), further in view of Walker et al. (New Zealand Journal of Botany, “Walker”), and further in view of Chairungsrierd et al. (European Journal of Pharmacology, “Chairungsrierd”). Applicant respectfully traverses this rejection.

The Examiner alleges that Müeller discloses to a homogenized composition of lipids with a particle size of 10 to 1,000 nm, but that Müeller does not disclose a biomass of lipid-containing microalgae (Office Action, pages 5-6). The Examiner further alleges that Kreitlow discloses lipophilic extracts that inhibit the growth of *S. aureus*, Caudales discloses that different strains of cyanobacteria contain different fatty acid compositions (Office Action, pages 6-7), and Caudales discloses fatty acid compositions of different strains of cyanobacteria (Office Action, page 7). Viseras is cited as a general reference of the state of the art of the claimed invention (Office Action, page 7), and Chairungsrierd, Walker and Jacob disclose various of the claimed biologically active compounds (Office Action, page 8). The Examiner asserts that the combination of references renders the instant claims obvious. Applicant respectfully disagrees.

A. The Combination of References does not Suggest Applicant’s Claimed Invention

Müeller

Similar to Müeller, one embodiment of the claimed invention is directed to a pharmaceutically active substance in association with a lipid-containing particle. However, Applicant’s invention (e.g. *see* claim 1) recites that the lipid-containing particles are produced from an unextracted suspension of one or more marine microorganisms. In direct contrast, Müeller is directed to lipid nanoparticles obtained from any source and purified. There is no requirement to utilize the whole of the microorganisms, or to use marine microorganisms. As recited in the instant claims, the marine microorganisms form a biomass which remains unextracted. Thus, Müeller does not disclose Applicant’s claimed invention, and the combination with the additional references does not render Applicant’s invention obvious.

Kreitlow

Kreitlow is directed to an observation that a strain of cyanobacteria contains an active biological substance. That substance was only identified in extracts (*see* abstract), and further, the substance was shown to comprise “antibiotically and/or cytotoxically active compounds” (*see* Kreitlow, page 63). As discussed above, Applicant’s biomass is not an extract, but also, and in direct contrast to Kreitlow, Applicant’s microparticles and

nanoparticles contain a pharmaceutical or cosmetic activity and said activity is not bactericidal (see claims 1 and 11, and also claims 22-27 and 31-34). Thus, Kreitlow does not disclose Applicant's claimed invention and, the combination with the additional references does not render Applicant's claims obvious.

Caudales

Caudales is cited in the Office Action for the purpose of showing that certain microorganisms, only some of which are marine microorganism, contain a lipid material (see Office Action, page 7). Applicant respectfully agrees that most all microorganisms contain a lipid component, but disagrees that the mere presence of lipid, which are ubiquitous throughout most all living organisms, provides any sort of motivation to one skilled in the art to produce lipid particles of marine microorganisms. Applicant's claimed invention is directed to marine microorganisms, and includes the unextracted biomass. This would be antithetical to any disclosure of Caudales and, thus, the combination of Caudales with the additional references does not render Applicant's claims obvious.

Viseras, Chairungsrilerd, Walker, and Jacobs

In the Office Action, Viseras, Chairungsrilerd, Walker, and Jacobs are cited to show that certain additives have pharmaceutically beneficial properties (see Office Action pages 7-9). For example, Viseras indicated that phyllosilicates and fibrous clay are included in pharmaceutical compositions (see Viseras abstract), Chairungsrilerd that mangostin has pharmaceutical properties (see Chairungsrilerd abstract), Walker that lichen contain biologically-active compounds (see Walker introduction), and Jacobs that thiocyanate has antifungal and antibacterial properties (see Jacobs abstract). Applicant respectfully notes that all of these materials are recited by Applicant as additives to the composition and methods of the claimed invention for exactly the purposes indicated. None of these references disclose a biomass with pharmaceutical properties; all refer to extracts, which again is antithetical to Applicant's claimed invention. Thus, none of these references in combination with the additional references cited in the Office Action suggest Applicant's claimed invention.

B. Reference in Combination and Individually Represent a "Teaching Against"

In addition, it is well established that a teaching against represents the strongest evidence of nonobviousness. *Kloster Speedsteel AB v. Crucible, Inc.*, 793 F.2d 1565 (Fed.

Cir 1986). That an inventor would achieve an invention by doing what those skilled in the art suggested should not be done strongly argues against any assertion of obviousness.

According to Mueller, the lipid particles are required to be pure (see Müller pages 162-163). In direct contract, Applicant's claimed composition is unpurified, being a un-extracted biomass. In other words Applicant's claimed composition recites that there be no such purification, and thus, Müller represents a clear teaching against. In fact, this represents a common aspect to all of the cited references. The particular pharmaceutical activity noted by the authors, and pointed out in the Office Action, is observed only from purified extracts. Applicant's claims require no such purification and, in fact, specifically state that the composition is a biomass. Thus, the cited references and especially Müller represent a teaching against, which is strong evidence of the nonobviousness of the claimed invention.

3. Surprising and Unexpected Results

It is well established that: "The ultimate determination of patentability must be based on consideration of the entire record...." MPEP §716.01(d), citing *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). That consideration must necessarily include Applicant's experimental results. Applicant respectfully submits that the claimed invention provides unexpectedly superior results.

Applicant respectfully notes that the authors or both Müller and Kreitlow would have thought Applicant's particles ineffective. Both are directed to purified extracts and, in the case of Müller, only pure lipid material. Surprisingly, and in contrast to both Müller and Kreitlow, and also conventional technology, Applicant's claimed composition is both effective and has surprising advantages that are non-bactericidal in the absence of added components.

Further, Applicant has shown in the Examples section that synergistic affects exist when the biomass of the claimed invention is coupled with known pharmaceutically active substances (e.g. see Examples 6 and 8-11). Applicant has also shown that synergistic effects are also observed when the composition of the invention is coupled with substances such as vitamin C (see Example 2 and Figure 1). Although vitamin C is not generally considered to be an antimicrobial, when couple with the composition of the invention of claim 1, the antimicrobial affects observed are synergistic. Such results would not have been predicted by

any combination of the cited references. Thus, the combination does not and cannot suggest Applicant's claimed invention and this rejection should be withdrawn.

In view of all of Applicant's assertions above, the rejection of claims 1-19 and 21-50, under 35 U.S.C. § 103(a), is overcome or moot and Applicant respectfully requests that it be withdrawn.

Conclusion

The application is now in condition for allowance and a Notice of Allowance is respectfully requested. If any further issues arise with regard to the prosecution of this application, the Examiner is requested to telephone the undersigned as convenient.

Should additional fees be necessary in connection with the filing of this Response, or if a petition for extension of time is required, the Commissioner is hereby authorized to charge **Deposit Account No. 14-1437 for any such fees, referencing Attorney Docket No. 9015.002.US**; and applicant hereby petitions for any needed extension of time not otherwise accounted for with this submission.

Respectfully submitted,
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